DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

'99 MAY -7 P3:42

Re: Neumega®
Docket No.: 98E-0615

MAY - 5 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,215,895, filed by Genetics Institute, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Neumega®, the human biological product claimed by the patent.

The total length of the regulatory review period for Neumega® is 1,854 days. Of this time, 1,513 days occurred during the testing phase and 341 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 30, 1992.

   The applicant claims October 25, 1992, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 30, 1992, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 20, 1996.

   FDA has verified the applicant's claim that the product license application (PLA) for Neumega ® (PLA 96-1433) was initially submitted on December 20, 1996.

3. The date the application was approved: November 25, 1997.

   FDA has verified the applicant's claim that PLA 96-1433 was approved on November 25, 1997.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Steven R. Lazar
Genetics Institute, Inc.
Legal Affairs
87 CambridgePark Dr.
Cambridge, MA 02140

DATE: MAY - 5 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Neumega®
Docket No. 98E-0615, FRDTS# OC99125

Attached is a FR Notice for the human biological product, Neumega®. This document has been internally reviewed and cleared by OHA.

Please note that Neumega® is a registered trademark. Therefore, the superscript "R" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

«FR_Track_No»

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Memorandum

Date: MAY - 5 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for Neumega®

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human biological product under the Docket Number **98E-0615** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,215,895**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98E-0615